



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/524,024

02/09/2005

Katsumi Ihara

2005-0097A

3975

513 7590 10/14/2008

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

ELLIS, SUEZU Y

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

10/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,024	<b>Applicant(s)</b> IHARA ET AL.	
	<b>Examiner</b> Suezu Ellis	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **FINAL REJECTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

### ***Drawings***

The drawings were received on July 10, 2008. These drawings are acceptable.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 6, examiner notes that the claim appears to be close-ended since applicant uses the term "consists of", however the term "and optionally" appears to contradict the "consists of". Further, the phrase "and optionally" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 103***

Art Unit: 1615

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO 01/87276) in view of Brantl et al. (US 4,826,686) and further in view of McQuinn (US 5,113,860).

With respect to claims 1 and 6, Kim et al. discloses a transmucosal patch containing fentanyl for transmucosal delivery, which comprises a drug layer containing fentanyl, an adhesive (maleic anhydride/vinyl ether copolymer) and thickener (hydroxyethyl cellulose) (pg. 10, lines 18-30). Kim et al. further discloses in Fig. 1, an impenetrable support layer (1) on the drug layer, however fails to expressly disclose the inclusion of a backing layer. However, it is well known in the art to include a backing on a support layer, as taught by Brantl et al. (col. 4, lines 13-17). It would have been obvious to one of ordinary skill in the art to include a backing layer in order to protect the patch from substantial disintegration over the time period which the patch is intended to remain adhered to the mucosal surface, as taught by McQuinn (col. 9, lines 5-12).

With respect to claim 4, the modified Kim et al. fails to expressly disclose the ratio of the adhesive and thickener being in the exact claimed range, however does disclose the adhesive being in the range of 0.1-15wt.% and the thickener being in the range of 0.1-20 wt.% (pg. 10, lines 20-23). Therefore, one of ordinary skill in the art

Art Unit: 1615

could attain the ratio in the range of 5:95 to 97:3. It would have been obvious to one of ordinary skill in the art to modify the ratio of adhesive to thickener of the modified Kim in order to attain a patch with desired properties (pg. 10, lines 22-30). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, USPQ 233.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of Brantl et al. and further in view of McQuinn and further in view of Yamaguchi et al. (US 5,820,877).

With respect to claim 2, the modified Kim et al. addresses all the limitations of claim 1, however fails to expressly disclose the fentanyl salt is fentanyl citrate. Yamaguchi et al. discloses a permucosal patch for delivering fentanyl citrate (col. 3, lines 59-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fentanyl salt to be fentanyl citrate, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of Brantl et al. and further in view of McQuinn and further in view of Miller, II et al. (US 2004/0086551).

With respect to claim 3, the modified Kim et al. addresses all the limitations of claim 1, however fails to expressly disclose the drug release rate from the drug layer is 50% within one hour. Miller, II et al. teaches a fentanyl patch having a drug release rate of 50% within one hour, as illustrated in Figs. 4 and 5. It would have been obvious to one of ordinary skill in the art to modify the drug release rate, as desired, in order to provide an effective immediate release of drug from the patch.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of Brantl et al. and further in view of McQuinn and further in view of Yamaguchi et al. and further in view of Miller, II et al.

With respect to claim 5, the modified Kim et al. addresses all the limitations of claims 1 and 2, however fails to expressly disclose the drug release rate from the drug layer is 50% within one hour. Miller, II et al. teaches a fentanyl patch having a drug release rate of 50% within one hour, as illustrated in Figs. 4 and 5. It would have been obvious to one of ordinary skill in the art to modify the drug release rate, as desired, in order to provide an effective immediate release of drug from the patch.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone/Fax Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615